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DATE MAILED: 04/28/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/081,051	02/20/2002	Anthony F. Barbet	UF-299XC1	1773
23557	7590 04/28/2004		EXAMINER	
	HIK LLOYD & SALIW	BASKAR, PADMAVATHI		
A PROFESSIO 2421 N.W. 411	ONAL ASSOCIATION ST STREET		ART UNIT	PAPER NUMBER
SUITE A-1 GAINESVILLE, FL 326066669			1645	
			DATE MAILED: 04/28/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

ASA.	Application No.	Applicant(s)				
Office Astion Commence	10/081,051	BARBET ET AL.				
Office Action Summary	Examiner	Art Unit				
	Padmavathi v Baskar	1645				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period we Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ib(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	rely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 05 Fe	ebruary 2004.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
リャース0 4)⊠ Claim(s) <u>1-7</u> is/are pending in the application.						
	4a) Of the above claim(s) <u>18-20</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-7</u> is/are rejected.	·					
7) Claim(s) is/are objected to.	Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examiner						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of	of the certified copies not received	d.				
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)					
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/21/03, 6/20/03.	6) Other:	ιτοτι Αρρικατίστι (Ε 10-152)				

## **DETAILED ACTION**

1. Applicant's response to restriction requirement and preliminary amendment filed on 2/5/04 is acknowledged.

#### Election

2. Acknowledgment is made of Applicant's election of Group I, claims 1-7 and 16 without traverse drawn to polynucleotide with respect to SEQ.ID.NO: 52.

### Status of Claims

3. Claims 1 and 7 have been amended.

Claims 8-17 have been canceled.

New Claims 18-20 have been added.

Claims 1-7 and 18-20 are pending in the application.

Claims 18-20 are drawn to an isolated polypeptide and a method of making a polypeptide. New claims are drawn to a non-elected invention, i.e., polypeptide, said election being made on 2/5/04 and are therefore withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-7 are under examination. A First Action on the Merits on these claims is issued.

#### **Priority**

Applicant's claim for domestic priority to provisional application 60/269,944 (2/20/010) under 35
 U.S.C. 119(e) is acknowledged.

## Information Disclosure Statement

5. Acknowledgment is made of  $1/\sqrt{2}$  Information Disclosure Statements filed 01/21/03 and 6/20/03. A signed copy of each is attached to this Office action.

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#### Claim Informalities

6. Claim 2 implies that the isolated polynucleotide sequence comprises more than one regulatory element (i.e., elements) and more than one expression system (i.e., systems)? Is this polynucleotide sequence in part expressed in more than one expression system having its own regulatory element? Or is the isolated polynucleotide sequence as set forth in SEQ.ID.NO: 52 as a whole expressed in different expression systems?

Claim 7 recites "a host cell comprising a polynucleotide sequence". Does applicant intend to mean an isolated host cell transformed by a vector comprising the polynucleotide sequence according to claim 1?

## Rejection(s) under 35 U.S.C. § 101

7. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

8. Claim 7 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. To overcome this rejection the Examiner suggests the amendment of the claims to include " isolated" so that it is "free of" relative to the natural source. ( see <u>Farbenfabriken of Elberfeld Co. v. Kuehmsted</u>, 171 Fed. 887, 890 (N.D. III. 1909) (text of claim at 889); <u>Parke-Davis & Co. v. H.D. Mulford Co.</u>, 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and <u>In re Bergstrom</u>, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

## Rejection(s) under 35 U.S.C. § 112, Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his/her invention

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10. Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague for the recitation of "an isolated polynucleotide sequence comprising SEQ.ID.NO: 52". The expression SEQ.ID.NO is generally used to identify a sequence. For the purpose of distinctly claiming the subject matter, it is proper to recite the claim as "an isolated polynucleotide comprising the nucleotide sequence SEQ.ID.NO: 52" Or "an isolated polynucleotide sequence as set forth in SEQ.ID.NO: 52".

Claim 2 is vague for recitation of "capable of causing the expression" It has been held that an element is capable of Forming a color is not a positive limitation but only requires the ability to perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69USPQ 138.

Claim 2 is rejected as vague for the recitation of "optionally", It is not clear how does one determine whether or not a polynucleotide sequence encoding a heterologous polypeptide is optional?

#### Remarks

- 9. Claims 1-7 are rejected.
- 10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the

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status of this application or proceeding should be directed to the receptionist whose telephone number

is (571) 272-1600.

Padma Baskar Ph.D.

4/13/04

LYNETTE R. F. SMITH SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600